

REMARKS

The non-final Office Action mailed May 7, 2004 has been received and carefully reviewed. Claims 1-17 stand rejected in the application. Claims 18-23 have been cancelled without prejudice as being directed to a non-elected invention. Claims 1, 5, 13, and 17 have been amended. New claims 24-31 have been added.

Reconsideration of the application as amended, and withdrawal of the present rejections are respectfully requested in view of the amendments to the claims and the following remarks.

Applicant affirms the verbal election with traverse to prosecute the invention of Group I, claims 1-17. As indicated above, Applicant has canceled claims 18-23 without prejudice.

Several Section 35 U.S.C. 103(a) rejections were presented in the Office Action, as follows:

Claims 1, 9 and 11-13 over *Norlander* et al. (U.S. 6,562,049) in view of *Dubrul* (U.S. 5,454,790); claims 2-4 and 14-16 over *Norlander* in view of *Dubrul* as applied to the aforementioned rejection, and in further view of *Wells* (U.S. 4,952,359); claims 5-8 and 17 over *Norlander* in view of *Dubrul* as applied to the aforementioned rejection, and in further view of *Gould* et al. (U.S. 4,586,923); and claim 10 over *Norlander* in view of *Dubrul* as applied to the aforementioned rejection and in further view of *Schaer* (U.S. 6,002,956).

Several provisional rejections were presented in the Office Action, under the judicial doctrine of obviousness-type double patenting, over copending Application Serial No. 10/041,911, as follows:

Claim 1, 5-7, 9-13 and 17 over specified claims in copending '911 application, in view of *Dubrul*; claims 2-4 and 14-16 over copending '911 application in view of *Dubrul* as applied to the aforementioned provisional rejection, and in further view of *Wells*; and claim 8 over copending '911 application in view of *Dubrul* as applied to the aforementioned provisional

rejection, and in further view of *Gould*.

Other provisional rejections were also cited in the Office Action under the judicial doctrine of obviousness-type double patenting, over copending Application Serial No. 10/014,735, as follows:

Claim 1, 5, 6, 9-13 and 17 over specified claims in copending '735 application, in view of *Norlander* and *Dubrul*; claims 2-4 and 14-16 over copending '735 application in view of *Norlander* and *Dubrul* as applied to the aforementioned provisional rejection, and in further view of *Wells*; and claims 7-8 over copending application in view of *Norlander* and *Dubrul* as applied to the aforementioned rejection, and in further view of *Gould*.

Norlander discloses a medical introducer apparatus that includes a pair of co-extending splittable introducer sheaths 11, 12. The Examiner concedes that *Norlander* fails to disclose a guide handle connected to the proximal end of an outer guide. The Examiner relies on *Dubrul* to supply this missing teaching.

To establish *prima facie* obviousness of a claimed invention, the Examiner has the burden of proving that three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure. All three of these criteria must be met in order to support a finding of *prima facie* obviousness of a claimed invention (see, e.g., MPEP § 2142).

Applicant has amended independent claims 1 and 13 to recite the additional feature of a steering member disposed along the outer guide. A distal end of the steering member is connected at a distal end of the outer guide, and a proximal end of the steering member is accessible at the proximal end of the outer guide, whereby application of a tensile force to the proximal end of the

steering member effects deflection of the distal end of the outer guide.

Neither *Norlander* nor *Dubrul*, alone or in combination, teaches or suggests a steering member disposed along the outer guide and as further described in Applicant's claims 1 and 13 as amended. *Dubrul* discloses an apparatus for catheterization access, but does not teach or describe a steering member or other steering mechanism.

Hence, only the *Norlander* reference of the asserted combination of *Norlander* and *Dubrul* provides the requisite teaching regarding steerability, with the understanding that knowledge possessed by one of ordinary skill in the art is relevant in a combination involving *Norlander*.

Norlander fails to teach a steering member or apparatus disposed along its outer introducer sheath 11. Rather, *Norlander* teaches an additional steerage member, such as a dilator 27, obturator, or deflecting tip device 74 for assisting with introduction and placement of the introducer sheaths 11, 12 (see, e.g., column 7, line 36 through column 8, line 43 and column 9, lines 1-40).

Norlander concedes that this additional steerage member is needed, otherwise "increased precisions would be required to advance the distal tip 16 of the outer introducer sheath 11 into the ostium 38 opening." Column 7, line 65 through column 8, line 1.

Norlander, alone or in combination with *Dubrul*, teaches an introducer apparatus that includes an outer introducer sheath 11, and inner introducer sheath 12, and an additional steerage member/device. The asserted combination teaches or suggests that these three telescoping tube structures, at a minimum, are needed to provide co-extendibility and steerability of the introducer sheath 12.

For example, *Norlander* describes its steerable/deflectable device 74 (shown in Figure 14) as a catheter type device over which inner and outer introducer sheaths 12, 11 can be advanced (i.e., three telescoping tube

structures). The steerable/deflectable device 74 includes a deflection control means 75 contained within the steerable/deflectable device 74, and is clearly not disposed along the outer introducer sheath 11.

In contrast, Applicant's claims as amended recite a guide catheter comprising a steering member disposed along the outer guide. Applicant's amended claims further recite that the steering member is connected at a distal end of the outer guide, which is clearly not the case in the *Norlander* device. Moreover, application of a tensile force to the proximal end of the steerable/deflectable device 74 of the *Norlander* device would cause deflection of the distal end of the steerable/deflectable device 74, not the outer introducer sheath 11.

Concerning the third criteria listed above which must be met to establish *prima facie* obviousness of a claimed invention, neither *Norlander* nor *Dubrul*, alone or in combination, teaches or suggests a steering member disposed along an outer guide. The asserted combination also fails to teach or suggest a steering member connected at a distal end of an outer guide. With particular reference to claim 13, this claim has been amended to recite that the inner guide has a stiffness relative to the outer guide sufficient to inhibit dislodgement of a payload as the outer guide moves in a proximal direction over the inner guide during outer guide retraction. The combination of *Norlander* and *Dubrul* fails to teach or suggest this feature. Applicant's claims as amended are patentable over the asserted combination for failure of the asserted combination to teach or suggest all the elements of Applicant's amended claims.

Applicant's amended claims recite a guide catheter comprising inner and outer guides each having open lumens, and a steering member disposed along the outer guide. Applicant's claimed catheter provides co-extendibility and steerability using only two telescoping tube structures, whereas *Norlander*, alone or in combination with *Dubrul*, requires three telescoping tube structures. Omission of an element (i.e., an additional telescoping tube structure) and

retention of its function (i.e., steerability) is an indicia of unobviousness (M.P.E.P. § 2144.04, section II-B, citing *In re Edge*, 149 USPQ 556 (CCPA 1966)).

Applicant notes that elimination of a third telescoping tube structure may advantageously provide for a reduction in inner and outer guide diameters, which can facilitate greater access into vessels of reduced size.

Applicant respectfully disagrees with the Examiner that it would have been a matter of obvious design choice to have modified *Norlander's* guide handle so as to have a distal end connected to the proximal end of the outer guide as taught by *Dubrul*. For example, claims 7, 8 and new claims 25, 26 recite features pertaining to a steering mechanism connected to the guide handle, which may enhance convenience of physician usage of the catheter. The asserted combination of references fails to teach or suggest these features. *Norlander* teaches that a deflection control means 75 of the steerable/deflectable device 74 extends proximally to a control handle, which is not shown. The handles 22 would not appear to be suitable for connecting with the control handle taught in *Norlander*. Other advantages associated with steerability may also be realized by the recited connectivity between the outer guide and the guide handle.

Applicant respectfully asserts that the combination of *Norlander* and *Dubrul* lacks the requisite motivation to support their combination in a manner suggested by the Examiner. For example, *Dubrul* is silent on catheter steering, and *Norlander* teaches a steering mechanism very different from that of Applicant's amended claims, as discussed above. One skilled in the art would not be motivated to combine the reference teachings in the manner suggested by the Examiner, particularly in view of the absence of steering teachings in *Dubrul*. Moreover, the asserted combination fails to provide a reasonable expectation that one skilled in the art could successfully arrive at Applicant's claimed apparatus. It is a requirement that actual evidence of a suggestion, teaching or motivation to combine prior art references be shown, and that this evidence be "clear and particular." *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999).

Broad conclusory statements regarding the teaching of references, standing alone, are not evidence. *Id.*

Because the combination of references fails to teach or suggest several of the above-identified limitations and because no motivation or suggestion to combine the references can be identified in the references themselves, and further because the asserted combination does not provide a sufficient basis to support a reasonable expectation of success, Applicant respectfully asserts that the Examiner has failed to establish *prima facie* obviousness of Applicant's subject matter recited in independent claims 1-17, as amended.

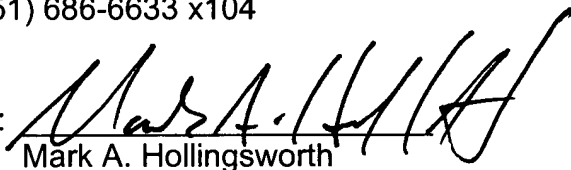
The teachings or suggestions of *Gould* and *Schaer*, when combined with those of *Norlander* and *Dubrul*, fail to supply the elements or motivation clearly missing in the *Norlander* and *Dubrul* combination with regard to various dependent claims. While Applicant does not acquiesce with any particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 13. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." M.P.E.P. §2143.03; *citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 2-12 and 14-17 are also allowable over the asserted combination of references.

Applicant notes the several provisional obviousness-type double patenting rejections set forth in the Office Action. Applicant believes these are now moot in view of the amendments to the claims.

It is believed that the pending and new claims 24-31 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,
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